REMARKS

I. Preliminary Remarks

Applicants gratefully acknowledge the Examiner's withdrawal of the 35 USC §112, first paragraph rejection of Claims 39-40.

II. 35 USC 101 Double Patenting Rejection

Claims 39 and 40 stand rejected under 35 USC 101, as "claiming the same invention as that of claims 1, 10 and 14 of prior U.S. Patent No. 6,774,117 B1." [Office Action dated February 1, 2007 ("Office Action"), page 3.] Applicants respectfully traverse, submitting that Claims 39 and 40 of the instant application are not identical to Claims 1, 10 and 14 of U.S. Patent No. 6,774,117 B1 ["the '117 patent"].

The Office Action goes on to state,

> The instantly claimed method of blocking *in vivo* expression of the MN gene in a human and treating neoplastic disease in a human by administering an MN antisense construct complementary to SEQ ID NO:5 is identical in scope with the methods of claims 1, 10 and 14 of prior U.S. Patent No. 6,774,117 B1.

[Office Action at page 3; emphasis added.] Applicants respectfully disagree, arguing that the methods of instant Claims 39 and 40 using MN antisense constructs are not identical in scope to the methods of Claims 1, 10 and 14 of the '117

patent, which comprise administering naked DNA in a "physiologically acceptable carrier".

The Manual of Patent Examining Procedure (MPEP) provides the criterion for a double patenting rejection at MPEP § 804, subsection IIA ["Statutory Double Patenting - 35 U.S.C. 101"], which reads:

> In determining whether a statutory basis for a double patenting rejection exists, the question to be asked is: **Is the same invention being claimed twice?** 35 U.S.C. 101 prevents two patents from issuing on the same invention. **"Same invention" means identical subject matter**. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1984); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957).
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> **A reliable test for double patenting under 35 U.S.C. 101 is whether a claim in the application could be literally infringed without literally infringing a corresponding claim in the patent.** *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970). **Is there an embodiment of the invention that falls within the scope of one claim, but not the other? If there is such an embodiment, then identical subject matter is not defined by both claims and statutory double patenting would not exist.** For example, the invention defined by a claim reciting a compound having a "halogen" substituent is not identical to or substantively the same as a claim reciting the same compound except having a "chlorine" substituent in place of the halogen because "halogen" is broader than "chlorine." On the other hand, claims may be differently

> worded and still define the same invention. Thus, a claim reciting a widget having a length of "36 inches" defines the same invention as a claim reciting the same widget having a length of "3 feet."

[MPEP § 804, IIA; emphasis added.]

The pertinent question, according to the above passage from the MPEP, is: "**Is the same invention being claimed twice? . . . [Wherein the] '[s]ame invention' means identical subject matter.**" Applicants respectfully but most adamantly point out that the claimed invention and that of the '117 patent are not identical, as will be shown in detail below. As the inventions of Claims 39 and 40 are not identical to those of Claims 1, 10 and 14 of the '117 patent, a terminal disclaimer should be sufficient to overcome a non-statutory obviousness-type double patenting rejection. As the Federal Circuit stated in In re Goodman, 11 F.3d 1046 [29 USPQ2d 2010, 2018-1019] (Fed. Cir. 1993):

> The double patenting determination involves two inquiries. First, is the same invention claimed twice? . . . This inquiry hinges upon the scope of the claims in question. . . . If the claimed inventions are identical in scope, the proper rejection is under 35 U.S.C. § 101 because an inventor is entitled to a single patent for an invention. . . .
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> . . . .
>
> If one claimed invention has a broader scope than the other, the court must proceed to a second inquiry: whether one claim defines

> merely an obvious variation of the other patent claim. Vogel, 422 F.2d at 441. Without a patentable distinction--because the pending claim defines merely an obvious variation of the patented claim--**the patentee may overcome the double patenting rejection by filing a terminal disclaimer**.

[Emphasis added.] Accompanying this response is a terminal disclaimer over U.S. patent No. 6,774,117 B1. Applicants respectfully submit that that terminal disclaimer would overcome a **nonstatutory** double patenting rejection based on the statutory double patent rejection.

Applicants respectfully refer to the above quote from MPEP § 804 for "[a] reliable test for double patenting under 35 U.S.C. 101 . . . [being] whether a claim in the application could be literally infringed without literally infringing a corresponding claim in the patent." The answer to that test for the subject claims is yes as shown below.

Claim 1 of the '117 patent reads:

> 1. A method of treating neoplastic disease and/or pre-neoplastic disease in a vertebrate, wherein said disease is associated with abnormal MN gene expression comprising inhibiting the expression of MN gene **by administering a MN antisense oligonucleotide in a physiologically acceptable carrier**, wherein said MN antisense oligonucleotide is complementary to SEQ ID NO: 5.

Claims 10 and 14 of the '117 patent similarly claim methods comprising "administering a MN antisense oligonucleotide in a

physiologically acceptable carrier". In contrast, Claims 39 and 40 of the instant application read:

> 39. A method of blocking in vivo expression of the MN gene in a human **by administering an MN antisense construct of claim 31.**
>
> 40. A method of treating neoplastic disease and/or pre-neoplastic disease in a human, wherein said disease is associated with abnormal MN gene expression, comprising inhibiting the expression of MN gene **by administering an MN antisense construct according to claim 31.**

[Emphasis added.] The "MN antisense construct according to claim 31" is one that comprises

> a nucleic acid sequence from which an MN antisense oligonucleotide is transcribable, wherein said nucleic acid sequence is operably linked to an expression control sequence in a vector, wherein said MN antisense oligonucleotide is complementary to SEQ ID NO: 5, and wherein said MN antisense construct shows antisense activity in an in vitro screening assay. . . .

[Preamble of Claim 31, in part.]

In pointing out the differences in scope between the claims in question, Applicants respectfully emphasize that 1) the phrase "physiologically acceptable carrier" of the prior '117 patent claims, within the context of the '117 specification, does not convey "nucleic acid constructs" to one of skill in the art; and 2) the antisense constructs of the instant claims comprise additional regulatory nucleic acids and

do not per se comprise the MN antisense oligonucleotides of the '117 patent claims, but must only express those MN antisense oligonucleotides.

1. "Physiologically Acceptable Carrier" versus "Nucleic Acid Constructs"

The "MN antisense construct according to claim 31" in instant Claims 39 and 40 is one "from which an MN antisense oligonucleotide is transcribable" [Claim 31 preamble], which is not the same thing as the "physiologically acceptable carrier" used to administer the MN antisense oligonucleotide of the '117 patent claims. The following are the two passages from the '117 patent specification referring to a "physiologically acceptable carrier":

> Such vaccine compositions will be combined with a **physiologically acceptable medium, including** immunologically acceptable diluents and **carriers** as well as commonly employed adjuvants such as Freund's Complete Adjuvant, saponin, alum, and the like.

[The '117 patent specification, Vaccines, page 96, line 25 to page 97, line 3; emphasis added.]

> Antibodies, appropriately labeled or linked to an imaging agent, can be injected in a **physiologically acceptable carrier** into a patient. . . .

[The '117 patent specification, Imaging Use of Antibodies, page 91, lines 17-19; emphasis added.] The "physiologically

acceptable . . . carriers" of the first passage above are categorized as a "medium" and grouped with "diluents", implying that the function of the carrier is simply to "carry" the molecule(s) in question, which is different in scope from a vector actively expressing molecules, i.e., antisense oligonucleotides. The vector is a mechanism providing a persistent supply of antisense oligonucleotides, which can potentially overcome problems of antisense oligonucleotide instability.

Therefore, Claims 39 and 40 which concern administering constructs "from which an MN antisense oligonucleotide is transcribable" differ in scope from Claims 1, 10 and 14 of the '117 patent which concern administering a antisense oligonucleotide in a physiologically acceptable carrier. In accordance with In re Goodman, supra, the instant Claims 39 and 40 are not identical in scope with Claims 1, 10 and 14 of the '117 patent, so a 35 U.S.C. § 101 double patent rejection does not apply.

2. "MN Antisense Oligonucleotides" versus "MN Antisense Construct from which an MN Antisense Oligonucleotide is Transcribable"

Further details confirm the differences in scope between the instant Claims 39 and 40 and that of Claims 1, 10 and 14 of the '117 patent. The MN antisense construct of

instant Claims 39 and 40 comprises 1) a nucleic acid sequence from which an MN antisense oligonucleotide is transcribable, and 2) an expression control sequence in a vector. In contrast, Claims 1, 10 and 14 of the '117 patent claim methods wherein "a MN antisense oligonucleotide in a physiologically acceptable carrier" is administered, wherein said MN antisense oligonculeotide is complementary to SEQ ID NO: 5 (full-length MN cDNA), which does not contain an "expression control sequence in a vector" of the instant Claims 39 and 40.

MPEP § 804, as quoted above, states that if there is an embodiment of an invention that falls within the scope of one claim but not within that of another claim, "then identical subject matter is not defined by both claims and statutory double patenting would not exist." The "reliable test for double patenting under 35 U.S.C. 101" of MPEP § 804 is in the context of **literal infringement**, that is, "whether a claim in the application could be **literally infringed without literally infringing** a corresponding claim in the patent." [MPEP § 804; emphasis added.]

Applicants respectfully submit that there are any number of embodiments that fall within the scope of instant Claims 39 and 40, that do not fall within the scope of Claims 1, 10 and 14 of the '117 patent. For example, a single-stranded vector comprising a MN sense oligonucleotide would provide a

template for transcription of an MN antisense oligonucleotide but such a construct itself would not contain a MN antisense oligonucleotide. Such an exemplary embodiment at the very least does not fall within the scope of Claims 1, 10 and 14 of the '117 patent. According to MPEP § 804, since such an exemplary embodiment of the invention falls within the literal scope of Claims 39 and 40, but not within the literal scope of Claims 1, 10 and 14 the '117 patent, "then identical subject matter is not defined by both claims and statutory double patenting . . . [does] not exist." [MPEP § 804.]

In summary, the scope of an "MN antisense construct from which an MN antisense oligonucleotide is transcribable" is different from that of an "MN antisense oligonucleotide in a physiologically acceptable carrier". As argued in the previous response dated January 4, 2007, because therapeutic methods using antisense constructs overcome potential drawbacks of those using naked DNA/RNA (e.g., no mechanism for persistence or stability of the antisense DNA/RNA), the claimed methods of Claims 39 and 40 would potentially work better than those using only the naked MN antisense DNA/RNA of the '117 patent claims.

As explained in detail above, Claims 39 and 40 do not claim the "same invention" as that of Claims 1, 10 and 14 of the '117 patent wherein the "same invention" means "identical subject matter" as defined by MPEP § 804. Also for the reasons

explained above statutory double patenting does not apply to the subject claims in accordance with the criteria of MPEP § 804.

As the Federal Circuit indicated in In re Goodman, supra, as a 35 U.S.C. § 101 double patenting rejection for claims of identical scope does not apply to the instant Claims 39 and 40 over Claims 1, 10 and 14 of the '117 patent, Applicants may overcome a nonstatutory obviousness-type double patenting rejection by filing a terminal disclaimer. Applicants respectfully conclude that the accompanying terminal disclaimer over the '117 patent would overcome such a nonstatutory double patenting rejection based upon Claims 1, 10 and 14 of the '117 patent. Applicants respectfully request that the Examiner reconsider and withdraw the subject **statutory** double patenting rejection, as well as the portent of a potential **nonstatutory** double patenting rejection that could be based on the subject rejection, in light of the above explanations and terminal disclaimer.

CONCLUSION

Applicants respectfully submit that Claims 31-35, 39-40 and 53-55 are in condition for allowance, and earnestly request that the claims be promptly allowed. If for any reason the Examiner feels that a telephone conference would expedite the prosecution of the subject application, the Examiner is

invited to telephone the undersigned Attorney for Applicants at (415) 981-2034.

The requisite Terminal Disclaimer fee under 37 CFR 1.20(d) is being paid by credit card and accompanies this response. Should any additional fees be determined to be necessary in connection with this response, Applicants respectfully request that any such additional fees be charged to Deposit Account No. 12-0615.

Respectfully submitted,

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